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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Manzer Durrani

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6451

44183 7590 10/19/2010
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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

10/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1646

CONTINUATION OF ADVISORY ACTION:

Continuation of 3. NOTE: New claims 72-74 would required substantial further consideration

Continuation of 7: Applicants' amendment will not be entered; however, if entered the proposed amendment would overcome the following rejections: 35 USC 112, first and second paragraphs.

Continuation of 11: The request for reconsideration has been considered but does NOT place the application in condition for allowance because: of the reasons previously set forth.

Applicants argue the Examiner has not provided reasoning or evidence to show why one of skill in the art would be led to the claimed invention based on the prior art disclosures. Additionally, the instant application presents unexpected results related to stability of AAT in the claimed formulations over time and at various temperatures. The arguments have been fully considered, but are not persuasive. First, there is no direct comparison between the instant invention and the prior art to show unexpected results. It is noted that no carbohydrate except trehalose was tested in the instant application. Further, as stated in the previous Office action, the prior art teaches using a carbohydrate such as trehalose, which US 6,267,958 called a lypoprotectant, in a formulation and in which inclusion of a carbohydrate enables the protein to essentially retain its physical and chemical stability and integrity upon lyophilization and storage (see previous Office action, last paragraph of p. 7). The use of an antioxidant, carbohydrate (particularly trehalose) and surfactant as part of a pharmaceutical composition was old and well known (*e.g.*, US 6,653,284). Even the combination of AAT with an antioxidant and carbohydrate (*e.g.*, US 5, 166,134) or carbohydrate and surfactant (*e.g.*, US 5,618,786) was known in the prior art. One of ordinary skill in the art at the time the invention was made, having access to the previously cited prior art would have found the invention obvious. It is maintained that all the claimed elements were known in the prior art and one of ordinary skill could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results. As a result, it is maintained for the reasons or record that the invention is obvious.

Art Unit: 1646

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire Kaufman, Ph.D.

/Claire Kaufman/

Patent Examiner, Art Unit 1646

October 14, 2010

/Lorraine Spector/

Primary Examiner, Art Unit 1647